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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Nina Rautonen

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1653

MAIL DATE

DELIVERY MODE

04/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/571,992	Applicant(s) RAUTONEN ET AL.	
	Examiner SHERIDAN MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 29-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A response and amendment were received and entered on February 1, 2011. All evidence and arguments have been fully considered. Claims 25-27 are cancelled. Claims 1-24 and 28-39 are pending. Claims 1-21 and 29-39 are withdrawn due to a previous requirement for restriction. Claims 22-24 and 28 are examined on the merits in this Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2011 has been entered.

Response to Amendment

3. The amendment to the claims filed on February 1, 2011 does not comply with the requirements of 37 CFR 1.121(c) because the claims listing does not include the text of all claims. Specifically, the text of the claims that are withdrawn are not included in the claims listing. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except

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when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. **The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).**

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled” or “not entered” may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended,” or “withdrawn” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn—currently amended.”

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original,” “withdrawn” or “previously presented” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn” or “previously presented.” Any claim added by amendment must be indicated with the status of “new” and presented in clean version, i.e., without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of “canceled” or “not entered.”

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as “canceled” will constitute an instruction to cancel the claim.

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(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a “new” claim with a new claim number.

Since the reply filed appears to be *bona fide*, and the claims that are currently under examination are clearly marked, the claims have been entered. Applicant is advised that a response to this Office action must include a new claims listing that includes the text of all pending claims in order to avoid abandonment.

Specification

4. Objections to the specification have been withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-24 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 22 recites a method of treating and/or preventing the side-effects associated with the administration of nonsteroidal anti-inflammatory drugs, which method comprises administering to the patient an effective amount of a microorganism, which microorganism at least increases the amount of a COX-1 mRNA in at least one

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cell of the subject, wherein the microorganism *Bifidobacterium* sp. 420. Claims 23 and 24 recite the method according to claim 22, wherein the microorganism modifies the amount of a thither cyclooxygenase mRNA in said cell and wherein the microorganism increases the amount of a COX-1 mRNA in said cell, whilst simultaneously decreases the amount of a COX-2 mRNA in said cell.

7. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the instant case, those factors deemed most relevant are the amount of direction and guidance presented, the presence or absence of working examples, and the predictability and unpredictability of the art.

8. The disclosure is not enabling for a method of increasing the amount of COX-1 mRNA in at least one epithelial cell of a subject because it does not present enough direction and guidance for one skilled in the art to use the invention with a reasonable expectation of success without undue experimentation. The disclosure does not provide any guidance or working examples wherein the *Bifidobacterium* sp. 420 are

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administered to a patient. The experiments of the disclosure that were conducted with an animal model state only that *Bifidobacterium* was used, and do not disclose a method of using the strain recited in the claims (see experiments 2 and 3 of the instant disclosure). Furthermore, in the experiments of the disclosure, the method of using *Bifidobacterium* did not result in a change in the expression profile of cox-1 (see last paragraph of experiment 3 in the instant disclosure). Thus, the properties recited in the claims are not supported by the working examples disclosed in the instant application. The identification of an agent that causes an effect in vitro does not adequately predict the effect of the agent when used in a subject. The unpredictability of the art, as evidenced by the lack of a change in COX-1 mRNA expression in the animal models disclosed in the instant specification, demonstrates that applicant did not have possession of the full extent of the instant claims at the time of the invention. Given these facts, one skilled in the art would be unable to predict whether the invention could be performed as claimed with a reasonable expectation of success.

9. Therefore, the disclosure of the instant application does not enable one skilled in the art to use the invention as claimed.

Claim Rejections - 35 USC § 103

10. Rejections under 35 USC 103 have been withdrawn due to applicant's arguments (see arguments filed on November 1, 2010 at p. 5, last paragraph and p. 7, par. 3).

Response to Arguments

11. Applicant's arguments with respect to the rejections under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651